UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,530	09/05/2003	Peter Distefano	13407-020001	9529

26161 7590 04/11/2006

FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER
LIU, SUE XU

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/656,530	DISTEFANO ET AL.	
	Examiner	Art Unit	
	Sue Liu	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, drawn to a method of screening for a compound from a library of compounds, classified variously, for example in class 530, subclass 300+.

II. Claim 9, drawn to a method of evaluating a compound for a modulatory effect on life span regulation or potential, classified variously, for example in class 435, subclass 7.1+. (Note: The claim language of step e) is convoluted and confusing.)

III. Claims 10-21, drawn to a method of screening for a compound from a library of compounds for a modulatory effect on life span regulation or potential, classified variously, for example in class 436, subclass 536.

IV. Claim 22, drawn to a method of formulating a compound for a pharmaceutical composition, classified variously, for example in class 424, subclass 198.1.

V. Claims 23 and 24, drawn to method of evaluating a compound using a cell, classified variously, for example in class 424, subclass 93.1.

VI. Claims 25-31, drawn to method of identifying a GH/IGF-1 axis antagonist or partial agonist, classified variously, for example in class 435, subclass 7.1+.

VII. Claim 32, drawn to method of evaluating an age-associated parameter or a subject treated with a test compound, classified variously, for example in class 424, subclass 184.1+.

VIII. Claims 33-35, drawn to method of identifying an agent that modulates lifespan regulation of an adult animal, classified variously, for example in class 424, subclass 93.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Groups I-VIII are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case the different inventions in Groups I-III and V-VIII direct to various distinct methods, because they use different steps, require different reagents and/or will produce different results. The invention of Groups II, III and VII direct to methods of evaluating a compound that would modulating life span of a cell or a subject, and requires the step of "evaluating an age-associated parameter of", which are step and/or reagent that are not required by any of the Groups I, IV-VI, and VIII. Groups II, III and VII are different from each other. For examples, Group III requires a library of compounds to be screened and Group II only requires one particular compounds; Groups III and II both require "evaluating interaction between the test compound and the GH/IGF-1 axis component," which is not required by Group VII method. Group I invention is drawn to a method of screening a library of compound for its on various parameter of various disorders, requires the step of contacting a compound to a cell, which are step and/or reagent that are not required by other groups (II, III, VII, VIII, and IV). Group V directs to a method of evaluating a compound, and requires steps

and/or reagents of "evaluating an age-associated parameter of the cell", which is not required by Group I and requires the reagent of "a cell", which is not required by groups (II, III, and VII). Group VI require the steps and/or reagents of "chemically modifying an agonist..." and "structural similarity to an agonist...", which are not required by other groups. Group IV method requires the steps and/or reagent of pharmaceutical formulation, which is not required by the other groups. Thus, inventions of Groups I-VIII are distinct, and restriction between the groups is proper.

3. Therefore, these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter. Even though some of the groups are classified in the same class/subclass, this has no effect on the non-patent literature search. The different methods and products will require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches will be coextensive. Therefore, these do create an undue search burden, and restriction for examination purposes as indicated is proper.

Species Election

4. This application contains claims directed to the following patentably distinct species of the claimed invention. Applicants are requested to further elect **a single ultimate species for <u>each</u>** of the following:

A.) A single specific GH/IGF-1 axis component. Applicants are further requested to elect a single specific selection of a GH/IGF-1 axis component **<u>OR</u>** a functional fragment thereof.

B.) A single selection of contact a compound to a cell **OR** a non-human animal model.

C.) A single specific species of compounds. (Note: a selection of compounds based on molecular weight ranges does not satisfy the requirement. Examples of species could be antibodies, or aptamers, etc.)

D.) A single specific species of a disorder. (**Note**: Applicants are requested to selected a single specific disorder and further specify to which general category (e.g. neurological disorder) the selected specific disorder belongs.)

E.) A single specific selection of a cell surface receptor **OR** a secreted molecule.

F.) A single specific and defined number of nucleotide mutations per nucleic acid sequence. (e.g. 4 mutations per nucleic acid sequence.)

G.) A single selection of an antagonist **OR** an agonist compound.

H.) A single specific selection of an in vitro contacting from a cell-based assay **OR** a cell-free assay.

I.) A single specific species of a subject.

J.) A single selection of an age-associated parameter.

K.) A single selection of a direct antagonist of a positively acting component **OR** a direct agonist of an inhibitor component of the GH/IGF-1 axis.

The species are distinct, each from the other, because their structure and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have

different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purpose as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SL
Art Unit 1639
3/28/06

MARK SHIBUYA, PH.D.
PATENT EXAMINER